Rocky Flats Plant
Quality Requirement (QR-2A)
REVISION 0
QUALITY ASSURANCE PROGRAM

APPROVED BY: for / H. P. Mann 7/23/93
General Manager — Print Name — Date
Rocky Flats Plant

Responsible Organization: Systems Quality Engineering Effective Date: 08/16/93

CONCURRENCE BY THE FOLLOWING DISCIPLINES IS DOCUMENTED IN THE QUALITY ASSURANCE MANUAL HISTORY FILE:

Administration and Planning
Engineering and Technology
Environmental Restoration Management
Environmental and Waste Management
Facility Management and Operations
Maintenance and Plant Support
Performance-Based Training
Safety, Safeguards, and Security
Standards, Audits, and Assurance
Transition Management

USE CATEGORY 4

ORC review not required

The following have been incorporated in this revision:

Reviewed for Classification
By K.V. Clowell V/NV
Date 7/21/93

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LIST OF EFFECTIVE PAGES

Pages	Effective Date	Change Number
1-17	08/16/93	

TOTAL NUMBER OF PAGES: 17

1. INTRODUCTION

Quality Assurance Programs (QAPs) are established to document and assure that the applicable requirements of the Quality Assurance Manual (QAM) are met by organizations, projects, and personnel that perform activities affecting quality. Quality Assurance Programs are planned, documented, implemented, maintained, and assessed to allow consistent interpretation and application of quality requirements for activities that affect quality. Quality Assurance Programs are delineated in Quality Assurance (QA) Plans. The QAP designates responsibilities; and provides for training; indoctrination and special process certifications; use of approved instructions; procedures and drawings; methods for resolving disputes involving quality; internal and independent verification of performance achievement; and corrective action.

Quality Assurance Plans describe the organizational and technical interfaces that relate to activities affecting quality. Quality Assurance Plans are written for programs, projects, and facilities. The QA Plan/Quality Assurance Management Plan (QAMP) is the formal means by which management documents how QA requirements will be applied to programs; that is, it provides the "blueprint" for how the QAP will operate. Moreover, the QA Plan/QAMP provides the basis or criteria for assessing the effectiveness of the QAP. The use of the word "plan" in this Quality Requirement will be general in nature and will apply to all scopes of planning.

The EG&G Rocky Flats Plant (RFP) QAP is documented through Policy 11-1, Quality Assurance Program; the Rocky Flats QAM; Program and Project QA Plans; and implementing procedures. The QAP is designed to allow management and operating personnel to plan, and safely accomplish mission related work activities under controlled conditions, utilizing established quality requirements based on a graded approach application.

Selective application and a graded approach for control of the following requirements should be considered based on the item's or activity's scope and importance, function, complexity, risk, consequences of failure, reliability, repeatability of results, and economic considerations.

2. PURPOSE

To establish the requirements for the EG&G RFP QAP. The QAP is established and maintained to assure that quality is achieved, and that work is performed in a consistent manner, in accordance with established requirements while protecting personnel, equipment, the environment, and the public.

3. SCOPE

These requirements apply to EG&G RFP and all subcontractors, including contracted services organizations. When subcontractors do not perform work in accordance with the Rocky Flats QAM, the applicable requirements shall be included within the subcontractor's EG&G RFP approved QAP.

The EG&G RFP QAP shall be sustained by management commitment and involvement at all levels. Senior management shall retain and exercise the responsibility for the scope and implementation of an effective QAP. Line management is responsible for the achievement of quality. Each individual is responsible for the quality of their work.

Senior management is responsible for QAP development, implementation, assessment, and improvement. The EG&G RFP QAP is based on criteria cited in DOE Order 5700.6C, and listed in the Quality Assurance Program Description (QAPD) contained in this manual. The QAPD describes how the criteria of DOE Order 5700.6C is implemented taking into consideration the risk/hazard associated with the work.

New QAP documents are submitted to the appropriate DOE Lead Program Secretarial Officers (PSOs) and are regarded as approved 180 days after submittal, including any modifications which have been made or directed by DOE during this period, or receipt of a letter, whichever occurs first.

Management may, at any time, make changes to the DOE-approved QAP. Changes to the QAP and associated documents are submitted to the appropriate DOE Lead Program Secretarial Officers (PSOs) and are regarded as approved 90 days after submittal, including any modifications which have been made or directed by DOE during this period, or receipt of a letter, whichever occurs first.

4. ELEMENTS

4.1 Quality Assurance Program

4.1.1 Senior management shall develop and issue a written QA policy statement which commits the organization to implement a formal QAP.

4.1.2 To accomplish activities that affect quality, a documented QAP shall be planned, implemented, assessed, and maintained in accordance with the requirements of this QAM, or portions thereof.

a. Activities affecting quality include, but are not limited to siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, constructing, installing, inspecting, testing, operating, maintaining, repairing, replacing, assembling, chemical processing, data acquisition, data analyzing, joining, planning, protecting, training, sampling, characterizing, modifying, decontamination, and decommissioning.

4.1.3 Each contractor shall have a defined QAP which shall specify authorities and responsibilities and include internal checks and balances.

4.1.4 The QAP shall describe the management system, including planning, implementation, scheduling, assessment, and cost control considerations required to assure quality objectives and requirements are met.

4.1.5 During development and implementation of the QAP appropriate standards shall be used and include and/or reference all of the policies and procedures, authorities, requirements, and guidance documents.

4.1.6 The program shall identify the activities and items to which it applies.

4.1.7 The establishment of the program shall include consideration of the technical aspects of the activities affecting quality.

4.1.8 The program shall provide for control over the quality of items, processes and activities affecting quality to an extent consistent with their risk and/or importance using selective application and graded approach methodology.

4.1.9 The program shall be established and operational at the earliest time, and prior to beginning the activities.

4.1.10 The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions including the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, appropriately implemented work sequence, and assurance that prerequisites for the given activity have been satisfied.

4.1.11 The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality and for verification of quality.

4.1.12 The program shall provide for indoctrination and training, as necessary, of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained in a timely manner.

4.1.12.1 See QR-2B for additional training and qualification requirements.

4.1.13 The system of job assignments shall ensure that adequate human resources are allocated to meet commitments.

4.1.14 Management shall take the necessary actions to ensure that the QAP is understood and implemented in a timely manner.

4.1.15 Management of those organizations implementing the QAP, or portions thereof, shall regularly and objectively assess and report on the adequacy of that part of the program for which they are responsible and shall assure its complete and effective implementation and implement needed improvements.

4.1.15.1 See QR-2C for additional Management Assessment requirements.

4.1.16 The QAP shall promote effective and efficient achievement of performance and quality objectives and the implementation of needed improvements.

4.1.17 The QAP shall be binding on the total organization and all personnel, including those having responsibility for planning and scheduling.

4.1.18 Senior management shall retain and exercise the responsibility for the scope and implementation of an effective QAP.

4.1.19 Line management shall be responsible for the achievement of quality.

4.1.20 Each individual shall be responsible for the quality of their work.

4.1.21 The organization shall establish criteria for developing individual program activity QAPs or combining similar activities under a single QAP when appropriate.

4.2 Pass-down of Requirements

4.2.1 There shall be a process for identifying both internal and external customers, for establishing and documenting customer requirements, and for renegotiation when requirements change.

4.2.2 The appropriate QA requirements and the activities for those QA requirements are to be defined in the program guidance and direction documents as appropriate.

4.2.3 These requirements are to be specified, along with other technical requirements, technical direction, and funding authorizations, as appropriate.

4.3 Quality Assurance Program Description (QAPD)

4.3.1 The QAPD shall describe how the criteria of DOE Order 5700.6C is implemented taking into consideration the risk/hazard associated with the work.

4.3.2 The QAP shall describe or provide reference to functional responsibilities and work such as:

a. planning;

b. training and personnel development;

c. preparing, reviewing, approving, and verifying designs;

d. qualifying suppliers;

e. preparing, reviewing, approving, and issuing instructions, procedures, schedules, and procurement documents;

f. purchasing;

g. verifying supplier work;

h. identifying and controlling hardware and software;

i. manufacturing;

j. managing and operating facilities;

k. calibrating and controlling measuring and test equipment;

l. conducting investigations and acquiring data;

m. performing maintenance, repair, and improvements;

n. performing assessments; and controlling records.

4.3.3 The description shall include the onsite and offsite organizational elements that function within the scope of the QAP.

4.4 Quality Assurance Plans/Quality Assurance Management Plans

4.4.1 The organization's QAP shall be described and documented in a Quality Assurance (QA) Plan/Quality Assurance Management Plan (QAMP) that has been reviewed and approved for implementation as a policy directive by authorized senior management.

4.4.2 The QA Plan/QAMP shall identify the programmatic activities of the associated organizations covered by the QAP and shall describe the organizational structure, Quality Assurance policies and procedures, functional responsibilities, levels of accountability and authority, and necessary interfaces.

4.4.3 The QA Plan/QAMP shall define and document how and when activities conducted at the technical/project level are planned, implemented, and assessed.

4.4.4 Initial estimates, used in planning, shall be based on sound data and assumptions relating to personnel, material/service costs, availabilities, and productivity.

4.5 Acceptance and Approval of Quality Assurance Programs (Implementing Plans and Descriptions)

4.5.1 The extent of formal planning required for each activity shall be determined by management.

4.5.2 A documented decision process shall be used to determine which activities require formal plans, to include quality plans applied to projects, functions, products, or organizational entities.

4.5.3 Plans shall be kept current and shall include requirements, milestones, and responsibilities for performing the work, identification of risks together with the means for addressing them, and controls to be applied.

4.5.4 Management shall obtain DOE approval of new QA Program documents prior to commencing work.

4.5.5 Management shall ensure that the EG&G RFP QA Program meets the requirements of this manual and shall re-submit the QA Program documents, together with an implementation plan, to the Lead Program Secretarial Officers (PSOs) for approval within 180 days after DOE Order 5700.6C becomes effective.

4.5.6 Changes made over the previous year to DOE-approved QA Program documents shall be submitted annually to the Lead PSO for review. The submittals shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised program continues to satisfy the requirements of DOE Order 5700.6C, Quality Assurance. Changes made to correct spelling, punctuation, or other editorial items shall not require explanation or submittal.

4.5.7 All Level 1 QA related documents (documents that define the QAP) generated shall be submitted to DOE Rocky Flats Operations (RFO), QA Organization, for review and concurrence.

4.6 Readiness Reviews

4.6.1 Readiness reviews shall be performed prior to major scheduled or planned work, and/or the restart of work to verify at least the following characteristics:

a. Work activity prerequisites have been satisfied;

b. Detailed technical and QA procedures have been reviewed for adequacy and appropriateness;

c. Personnel have been suitably trained and qualified; and

d. The proper equipment, material, and resources are available.

4.7 Process Quality

4.7.1 Systems shall be established for documenting procedures, for monitoring processes, and for implementing error prevention and continuous improvement techniques.

4.7.2 Systems shall be established for specifying documentation and records control, including retention periods and assurance of records retrievability.

4.8 Significant Technical Documentation and Data

4.8.1 Significant technical documentation and data shall be defined in the appropriate planning documentation.

4.8.2 Significant documentation or data, such as program or project management plans, development or test plans, results data, test reports, and permit applications are to be submitted to the next higher level in the organizational hierarchy for review and evaluation.

4.8.3 Draft copies of these documents are to be submitted, reviewed, and approved or accepted as appropriate prior to implementation or issuance.

4.8.4 Any inadequacies or problem areas are to be resolved with the performing organization.

4.9 Quality Improvement

4.9.1 All personnel shall be granted the freedom and authority to stop work until effective corrective action is taken.

4.9.2 Responsibility and authority to stop unsatisfactory work shall be assigned such that planning and schedule considerations do not override safety considerations.

4.9.3 For additional quality improvement requirements, see QR-20, Quality Improvement.

4.10 Nonconformance and Corrective Action

4.10.1 The system established for detecting and correcting deficiencies shall be documented through the QAP.

4.10.2 There shall be timely disposition and documentation of nonconforming material.

4.10.3 The root cause(s) of the nonconforming material shall be identified and corrective actions taken to minimize the probability of recurrence.

4.10.4 Significant nonconformances of EG&G Rocky Flats Plant activities are to be reported to RFO.

4.10.5 Operating contractors are required to respond to all RFO assessment reports as soon as specified by the originating organization.

4.10.6 EG&G Rocky Flats Plant organizations are to provide the DOE-RFO Quality Assurance Organization with information on all corrective actions taken in response to internal and external assessments, evaluations, and other reviews. This may include electronic responses to a computerized system maintained by DOE-RFO Quality Assurance Organization. The following information shall be provided:

a. Identification of the deficiency

b. Root Cause Analysis identifying the basis of the deficiency (as specified by DOE-RFO Quality Assurance Organization)

c. Tracking information from deficiency identification to corrective action closure

d. Monthly reporting of status of corrective action

e. Notification of corrective action completion

4.10.7 The quality organizations are required to provide a single point of contact for all DOE-RFO Quality Assurance Organization assessment reports, regardless of which organization is to complete the corrective action.

4.11 Rights of Access

4.11.1 RFO contractors', subcontractors', and suppliers' facilities shall be accessible during normal working hours for the purposes of audit, surveillance, inspection, or other oversight activities.

4.12 Plans and Schedules for Oversight Activities

4.12.1 Long-range and near-term plans and schedules for reviews, surveillances, audits, and management assessments of internal and contractor or subcontractor activities shall be submitted to the next higher level in the organizational hierarchy.

4.12.2 Long-range and near-term plans and schedules shall be used in planning oversight activities (copy to RFO of annual/quarterly plans).

4.13 Oversight Activities Reports

4.13.1 Reports of audits and management assessments are to be submitted to the next higher level in the organizational hierarchy with a copy to DOE-RFO Quality Assurance Organization

4.13.2 Reports of surveillance activities and reviews that address significant programmatic issues are to be submitted to the next higher level in the organizational hierarchy, and summaries reported to DOE-RFO Quality Assurance Organization.

4.14 Annual Program Assessments

4.14.1 An independent annual management assessment of the adequacy, effectiveness, and implementation of the EG&G RFP QAP shall be performed and documented. A copy of the assessment report shall be submitted to the General Manager of EG&G RFP and to the Manager, RFO.

5. SUPPLEMENTAL ELEMENTS

5.1 Environmental Programs

5.1.1 Quality Assurance Program Description

5.1.1.1 The QAP shall include provisions to assure, when implemented effectively, that environmental data of the quality needed are produced and documented and that engineered environmental systems are designed, constructed, and operated to fulfill their intended purposes.

5.1.1.2 A QAP for environmental data operations and engineered environmental systems shall include two levels of management controls:

a. Organizational or institutional level. All activities that support common or standardized functions including management assessment, personnel qualifications and training, procurement policies, and document control, shall fall under management systems at the organizational level. These common functions establish the framework for performing work.

b. Technical/project level. The technical or project level consists of the project-specific QAP activities necessary to produce the desired type and quality of product within the framework defined by and shall be used in conjunction with the functions defined at the organizational level.

5.1.1.3 The QAP shall apply to environmental data operations and to the design, construction, and operation of engineered environmental systems.

5.1.1.4 Application of the QAP to individual projects shall be described in Quality Assurance Project Plans (QAPP) along with the project-specific attributes.

5.1.2 Planning and Scoping

5.1.2.1 The DOE RFI 5700.6, Rev. 0, Section 10.b has mandated EPA QAMS-005/80, "Interim Guidelines and Specifications For Preparing Quality Assurance Project Plans", as requirements applicable to EG&G Rocky Flats Plant. EG&G Rocky Flats Plant is required to follow the guidelines and specifications for Project Plan preparation, review and approval, for all projects involving environmental measurements.

5.1.2.2 All projects involving the generation, acquisition, and use of environmental data shall be planned and documented.

5.1.2.3 Planning shall include, before the development of detailed plans, determination of the type and quality of data needed for characterization of environmental processes and conditions.

5.1.2.4 The type and quality of environmental data needed for their intended use shall be defined and documented using the EPA Data Quality Objective (DQO) process (5) or its equivalent.

5.1.2.5 Determination of the type and quality of environmental data needed shall involve key users of the data as well as those responsible for activities affecting data quality.

5.1.2.6 Results of planning activities shall be subject to review and approval according to QAP requirements and line management decisions.

5.1.2.7 Project planning shall be coordinated among participating organizations and shall include the following elements:

a. Definition of program/task scope and objectives and listings of the primary requirements and activities involved in the work. When appropriate, this includes the definition of the precise problem and the associated action to be taken.

b. Identification of the specific environmental data to be collected and analyzed, including those data that measure the success or failure of the project.

c. Identification of applicable technical, regulatory, or program-specific quality standards, criteria, or objectives such as acceptable sampling and measurement uncertainty, and identification of procedures for quality verification.

d. Identification of personnel, equipment (including field and laboratory testing equipment, along with performance and calibration requirements), and other resources required to perform activities needed.

e. Identification of controlled conditions required for the collection and analysis of environmental samples and data.

f. Determination of assessment tools needed (i.e., program technical reviews, peer reviews, surveillances, and technical audits as needed and/or specified by the QAP).

g. Identification of methods or procedures for field and laboratory sampling, testing, and analysis activities, as well as the appropriate mechanism for making changes to sampling and analysis plans produced.

h. Definition of records required.

5.1.3 Work Processes and Operations

5.1.3.1 During planning, line management shall be required before the initiation of significant project activities to identify the customer(s) for the results and to determine the overall project scope of the work and the cost and schedule constraints within which project activities are required to be performed.

5.1.3.2 Planning shall be conducted according to a "graded approach" (e.g., the Data Quality Objectives (DQO) Process), which defines a level of QA commensurate with the importance or intended use of the work results.

5.1.3.3 Planning shall take into consideration any special controlled conditions to ensure that objectives are satisfactorily achieved.

5.1.3.4 Work shall be implemented in a sequence consistent with the need for completion of prerequisite activities.

5.1.4 Design of Data Collection Operations

5.1.4.1 The results of the design process shall be documented in a Quality Assurance Project Plan (QAPP) or other planning documents according to the requirements of the QAP and as found necessary or appropriate by line management.

5.1.4.2 The QAPP and/or other planning documents shall be reviewed and approved by designated persons (e.g., peer reviewers), who, together, are technically capable of evaluating all aspects of the sampling and analysis plan(s) and the QAPP, and are other than the individuals who designed the data collection process.

5.1.4.3 When multiple organizations participate in a single project, the approved QAPP and other planning documentation shall be binding on all participating groups and shall document the QA/QC responsibilities of each participant.

5.1.5 Design, Construction, and Operation of Engineered Environmental Systems

5.1.5.1 Activities and projects involving the design, construction, and operation of engineered environmental systems shall be planned and documented according to the elements of this manual.

5.1.5.2 Planning shall be required, before the development of detailed designs, determination of the appropriate design criteria/bases required for the engineered environmental systems.

5.1.5.3 Planning activities shall be conducted such that the type and quality of inputs to design, construction, and operation are defined and documented.

5.1.5.4 Project planning shall be coordinated among organizations participating in the activities and shall include the identification of the following elements as a minimum:

a. Program/task scope and objective, and a listing of the primary activities involved.

b. Specific engineering systems components to be designed, fabricated, constructed, and operated.

c. Technical, performance, and quality standards, criteria, or objectives.

d. Personnel, equipment, and other resources required.

e. Program technical reviews, peer reviews, surveillances, technical or QA audits, and other assessment processes.

f. Project and Quality Assurance Records required.

5.1.5.5 Planning activities shall be documented to the extent necessary to assure that participants in the engineering systems design, construction, and operation are informed of all requirements of the project in a timely manner.

5.1.5.6 Documentation of project and activity planning shall include the appropriate use of work plans, QAPPs, design criteria, schedules, organization charts, and other such document types appropriate to the circumstances.

5.1.6 The Rocky Flats Interagency Agreement, dated January 22, 1991, shall be reviewed and addressed in all QA plans, project plans, and work packages as specific sections or subsections apply.

5.1.7 Additional Environmental/Waste Program Quality Assurance/Quality Control requirements not delineated within the EG&G Rocky Flats QAM which must be met by affected Rocky Flats organizations when applicable are:

a. The Interagency Agreement (Part 33) for sampling and analysis for CERCLA and RCRA investigations;

b. DOE Order 5400.1 for CERCLA investigations;

c. Part IV of the RCRA Part B permit and SW-846 for waste characterization sampling analysis and statistical modeling;

d. NVO-325 for LLW processing, handling, and transportation to NTS;

e. WIPP requirements documents (e.g., DOE/WIPP-069, etc.) for processing, handling, storage, and transportation under DOE 5820.2A; and

f. 10CFR71 Subpart H for users of the TRUPACT-II vessel and for any other radioactive waste package required to be licensed by the NRC.

5.2 War Reserve (WR)

5.2.1 Early Involvement

5.2.1.1 Quality shall be an integral part of product and process design and development.

5.2.1.2 Quality planning shall provide for the timely identification and evaluation of key elements that are critical to program success, and shall provide objective means to measure design, product and process maturity and readiness for production.

5.2.2 Transition to Production

5.2.2.1 The quality system for preproduction shall include procedures for conducting reviews of manufacturing, inspection processes, and completeness of design definition.

5.2.2.2 The extent of the reviews shall be commensurate with the risk associated with failure to meet the requirement.

5.2.2.3 The determination of the risk shall be documented.

5.2.2.4 The purpose of these reviews is to ensure that production will be accomplished under controlled conditions.

5.2.2.5 The preproduction quality program shall, as a minimum, validate that:

a. The product definition is well documented, complete, and unambiguous;

b. Production processes have been fully developed in compliance with defined requirements and are thoroughly characterized and documented;

c. Adequate manufacturing, inspection, and acceptance procedures are documented and appropriate configuration management procedures are used;

d. Operating personnel are properly trained to perform required functions.

5.2.2.6 Qualification test plans shall be developed to assess that processes are stable and capable of producing product which consistently meets design requirements with minimum variation and perform consistently over their entire operational environment.

5.2.2.7 To the extent practical, statistical techniques including design of experiments, shall be utilized to support the test matrix and to systematically identify and eliminate product and process deficiencies.

5.2.2.8 These plans and methods shall make effective use of data and resources from process development efforts.

5.2.2.9 Performance indicators, such as process capability indices, yield rates, and the cost of nonconformance, shall be estimated and documented.

5.2.2.10 This information shall be used for evaluating initial processing activities, and shall provide a basis for continuous improvement.

5.2.3 Parts and Material

5.2.3.1 Provisions for control of material produced during preproduction shall be established.

5.2.3.2 These provisions shall include the identification and manufacturing and inspection status of materials.

5.2.3.3 These controls shall be established and maintained from procurement through the entire process of manufacturing, inspection, packaging, shipping, storage and testing.

5.2.3.4 Documented evidence of conformance to the product design definition shall be maintained.

5.2.4 The DOE/AL, Quality Policy and Operating Instruction Manual for Product Acceptance shall be reviewed and addressed in all quality assurance plans and work packages as specific sections or subsections apply. The QC-1, Quality Criteria and QC-2, Quality Criteria has been included in this Quality Assurance Manual.